PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Eric A. Johnson et al.

Appln. No. 08/458,019 Group Art Unit: 1808

Filed: 1 June 1995 Examiners: H. Lilling

For: PROCESSES FOR IN VIVO PRODUCTION OF ASTAXANTHIN AND PHAFFIA RHODOZYMA YEAST OF ENHANCED ASTAXANTHIN CONTENT

REQUEST FOR RECONSIDERATION

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

This Request for Reconsideration is responsive to the Office Action mailed 18 October 1995. Attached hereto and herein incorporated by reference is a Petition for Extension of Time for a three-month extension making the due date for response 18 April 1996.

In Item 17 on page 2 of the Office Action, the specification is objected to and in Item 18 at the bottom of page 4 of the Office Action claims 25-34 are rejected under 35 USC § 112, first paragraph.

The Examiner takes the position that additional strains are required to practice the invention as claimed. The Examiner acknowledges that the statute can be satisfied by a repeatable method set forth in the specification.

The objection and rejection are traversed for the following reasons.

The instant specification teaches in great detail a repeatable method for obtaining Phaffia mutants with a high astaxanthin content. The instant specification teaches that the starting material may be a wild-type strain or may be a mutant strain already producing high levels of astaxanthin than found in a wild-type strain.

Wild-type strains are available to the public, for example, through the ATCC, the relevant pages listing the available wild-type strains being of record in the instant case and in the earlier filed parental cases.

Also, two Phaffia strains expressing higher levels of astaxanthin than found in wild-type strains are on deposit at the ATCC and are freely available to the public. A copy of the deposit receipt relating to those two strains is of record.

As noted in the first full paragraph on page 15 of the instant specification, the invention can be practiced by subjecting a naturally occurring or a mutated strain of Phaffia to the selection agents as taught therein.

The specification teaches a variety of agents within the scope of the instant invention that can be used to obtain mutant yeast expressing higher levels of astaxanthin. For example, as noted in Figure 2, one strain of yeast was treated with antimycin to yield a mutant producing high levels of astaxanthin and then that mutant was treated also with antimycin to yield a second strain producing

higher levels of astaxanthin. Similar results were obtained on multiple, sequential treatment with nitrosoguanidine. Thus those experiments depicted in Figure 2 teach use of a naturally occurring starting material and a mutant starting material as taught in the instant invention.

As noted at pages 15 et seq., various strains producing enhanced levels of astaxanthin were produced, see Figure 2, the accompanying text in the instant specification and the working examples.

Appended to the amendment filed 16 December 1993 in parent case U.S. Ser. No. 067,797, is a copy of a Declaration under 37 CFR 1.132 providing additional data demonstrating the reproducibility of the instant invention.

In the several experiments disclosed in the declaration, a plurality of strains of high levels of astaxanthin production were obtained using different strains as starting materials.

As noted in the *In re Marzocchi* et al. decision, the Patent Office should be concerned with the accuracy of a generic term and not its breadth. 169 USPQ 367 (CCPA 1971). The *Marzocchi* decision also teaches that the first paragraph of 35 USC § 112 requires nothing more than objective enablement. That aim can be met by broad terminology or by the use of illustrative examples.

Clearly the instant application teaches a method for producing in a reproducible fashion yeast with enhanced astaxanthin content

and the instant application provides a plurality of yeast with those characteristics.

The law also holds that an assertion by the Patent Office that the enabling disclosure of the instant invention is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Bowen*, 181 USPQ 48 (CCPA 1974); *In re Arnbruster*, 185 USPQ 152 (CCPA 1975).

As stated repeatedly in the record, the instant invention teaches in clear and distinct terms a reproducible method for making Phaffia with enhanced astaxanthin content. A plurality of examples obtained by the method taught in the instant specification are set forth in the instant specification.

There is no evidence of record to doubt the reproducibility of the method disclosed in the instant application nor is there any legally or technically tenable reasoning to demonstrate that the instant invention is not reproducible. Numerous examples of yeast of enhanced astaxanthin content are documented in the record.

Clearly, the instant specification objectively and sufficiently teaches a repeatable method for making and for using the invention as claimed. Hence the instant specification is in full compliance with 35 USC § 112. There is no evidence of record to establish a prima facie case of non-enablement and to maintain

such an unsupported position is highly prejudicial to the real party of interest, a small American biotechnology company.

Withdrawal of the objection and rejection is necessary and requested respectfully.

In Item 19 at the bottom of page 5 of the Office Action, claims 25-34 are rejected under 35 USC § 102(b) or § 103 over U.S. Pat. No. 5,356,810.

U.S. Pat. No. 5,356,810 has an effective filing date of 12 November 1989. Referring to the continuing data of the instant application, current U.S. Ser. No. 458,019 is, in part, a continuation of U.S. Ser. No. 067,797, which is a continuation of U.S. Ser. No. 873,120 which is a divisional of U.S. Ser. No. 399,183 filed 23 August 1989.

Hence, U.S. Pat. No. 5,360,810 is not an effective reference against the instant invention, the rejection is improper and withdrawal thereof is required.

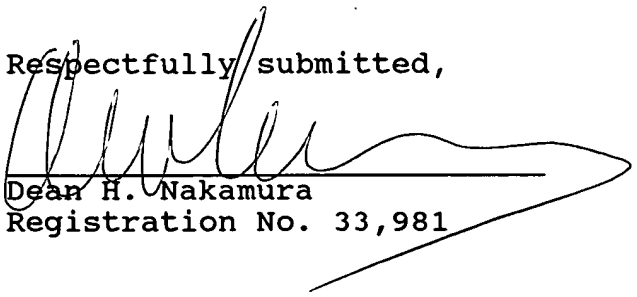
CONCLUSION

The instant application is in condition for allowance. Reexamination, withdrawal of the improper objection and rejections and early notification of allowance are requested respectfully.

Applicants hereby petition for any extension of time which may

so that a hasty resolution and allowance can be obtained without further delay.

Respectfully submitted,



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